Notice of Allowability	Application No.	Applicant(s)	
	10/696,487	BUCHHOLZ ET AL.	
	Examiner	Art Unit	
	Susan Ungar	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☐ This communication is responsive to *Amendment filed 12/10/07 and Interview of 1/14/08*.

2. ☒ The allowed claim(s) is/are *1, 2, 14, 15, 16, now renumbered 1-5- respectively*.

3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☒ None of the:
      1. ☒ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: *as of 1/17/08*.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

Susan Ungar
Primary Examiner
Art Unit: 1642

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 12, 2007 are acknowledged and has been entered. Claims 1-3 have been amended, claims 4-12 have been canceled and new claims 13-17 have been added. An action on the RCE follows.

2 Claims 1-3, 13-17 are pending and currently under examination.

3. An Examiner's Amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 C.F.R. ∋ 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the Issue Fee.

4. The application has been amended as follows:

In the claims:

Claims 1 and 2 were replaced with the following:

1. (Currently amended) A method for determining the presence or absence of pancreatic cancer in a patient comprising:

(i) obtaining a biological sample from ~~a~~ said patient;

(ii) detecting, in the sample, mRNA which is capable of being used in the production of ~~a~~ the sequence consisting of SEQ ID NO: 1; and

(iii) comparing the amount of mRNA detected with a predetermined standard value indicating the decision line for tumor-induced or non-tumor-induced ~~UKW~~ expression or presence ~~in the cell~~ of mRNA which is capable of being used in the

production of the sequence consisting of SEQ ID NO: 1 and therefrom determining the presence or absence of pancreatic cancer in the patient.

2. (Currently Amended) A process for determining whether or not a test sample of tissue or fluid of a patient contains pancreatic tumor cells wherein the test sample and a second sample originating from non-pancreatic-tumor cells from the same individual or a different individual of the same species are used, ~~which process comprises the following steps:~~ wherein the samples are assayed for mRNA which is capable of being used in the production of the sequence consisting of SEQ ID NO: 1 with a probe selected from the group consisting of :

(i) the nucleic acid consisting of SEQ ID NO:1 or a fragment thereof, said fragment consisting of a nucleotide sequence comprising 50 contiguous nucleotides of SEQ ID NO:1; and

(ii) a nucleic acid consisting of a polynucleotide which is 100% complementary to said nucleic acid consisting of SEQ ID NO:1 or said fragment thereof;

wherein determination of approximately 15 fold to approximately 60 fold greater level of mRNA which is capable of being used in the production of the sequence consisting of SEQ ID NO: 1 in the test sample compared to the level of mRNA which is capable of being used in the production of the sequence consisting of SEQ ID NO: 1 in the second sample, indicates that said test sample contains pancreatic cancer cells.

~~(a) incubating nucleic acids contained in each respective sample under stringent hybridization conditions with a nucleic acid probe which is selected from the group consisting of:~~

~~(i) the a nucleic acid sequence consisting of SEQ ID NO: 1, or a fragment~~

~~thereof, said fragment comprising 50 contiguous nucleotides of SEQ ID NO: 1;~~

~~(ii) a nucleic acid sequence which is 100% complementary to any nucleic acid sequence of (i);~~

~~(iii) a nucleic acid sequence which is capable of hybridizing under high stringent hybridization conditions with the sequence of (i); and~~

~~(iv) a nucleic acid sequence which is capable of hybridizing under high stringent hybridization conditions with the sequence of (ii);~~

~~(b) determining the approximate amount of hybridization of nucleic acids present in each respective sample with said probe, and~~

~~(c) comparing the approximate amount of hybridization present in said test sample to an approximate amount of hybridization present in said second sample to identify whether or not the test sample contains an approximately 15-fold to approximately 60-fold greater level of hybridization than does said second sample and therefrom determining whether the test sample contains pancreatic tumor cells;~~

~~said stringent hybridization conditions being conditions involving washing said nucleic acids with a solution of 5x SSC, 0.5% SDS, 1.0 mmol/l EDTA, pH 8.0, then hybridizing said nucleic acids at 50 to 60°C in 5x SSC overnight, then washing said nucleic acids at room temperature for 40 minutes with 2x SSC containing 0.1% SDS and afterwards washing said nucleic acids with 0.1x SSC, 0.1% SDS at 50°C for 40 minutes with one change of fresh solution;~~

~~said high stringent hybridization conditions being conditions involving washing said nucleic acids with a solution of 5x SSC, 0.5% SDS, 1.0 mmol/l EDTA, pH 8.0, then hybridizing said nucleic acids at 65 to 70°C in 5x SSC overnight, then~~

~~washing said nucleic acids at room temperature for 40 minutes with 2x SSC containing 0.1% SDS and afterwards washing said nucleic acids with 0.1x SSC, 0.1% SDS at 50°C for 40 minutes with one change of fresh solution.~~

Claim 16 was amended as follows: after "according to claim" the number "3" was deleted and the number --2-- was substituted therefore.

Claims 3, 13 and 17 were canceled.

5. Authorization for this Examiner's Amendment was given in a telephone interview with Gene Yao on January 17, 2008.

6. Any comments considered necessary by applicant must be submitted no later than the payment of the Issue Fee and, to avoid processing delays, should preferably **accompany** the Issue Fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (703) 305-2181. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (571) 272-0837. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached at 571-272-0832. The fax phone number for this Art Unit is (571) 273-8300.

Susan Ungar, PhD
Primary Patent Examiner
January 17, 2008